Notice of Allowability	Application No.	Applicant(s)	
	10/623,317	MICHELI, BRIAN R.	
	Examiner	Art Unit	
	Joseph W. Drodge	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Amendment filed February 9, 2007*.

2. ☒ The allowed claim(s) is/are *9-17 and 32-60, now renumbered claims 1-38*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *02142007* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Okey on February.

The application has been amended as follows: Claim 9 has been amended as follows: --

9. (Currently amended) A system for providing peritoneal dialysis to a patient, the system comprising:

a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity;

a fluid circuit in fluid communication with the catheter thereby defining a closed fluid path capable of circulating a therapy fluid into, through and out of the peritoneal cavity;

a first supply of the therapy fluid including a dialysate coupled to the fluid circuit;

a cycler that pumps the dialysate into the fluid circuit and circulates the dialysate along the closed fluid path during a treatment period to remove a therapeutically effective amount of solutes and ultrafiltrate from the patient;

a second supply of the therapy fluid including an osmotic agent solution coupled to the fluid circuit wherein the cycler can pump the second supply of fluid into the fluid circuit during the treatment period;

a cleaning device coupled to the fluid circuit wherein the cleaning device is capable of removing solutes including at least a portion of urea from the therapy fluid as it circulates along the closed fluid path;

a reservoir coupled fluidly to the fluid circuit via the cycler and one or more pumps and branching off [of] the closed loop [such that the cycler can move] for moving fluid at a controlled flowrate from the fluid circuit to the reservoir and from the reservoir to the fluid circuit, and wherein the reservoir is adapted to provide a variable increase in volume capacity to the fluid circuit allowing the system to compensate for an increase in fluid volume in the fluid circuit during treatment; and

a discharge path coupled to the fluid circuit allowing the fluid circuit to be drained of fluid after the treatment period. -- .

Claim 32 has been amended as follows: --

32. (Currently amended) A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication with a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a source of the fluid including a dialysate to the fluid circuit;

circulating the dialysate along the closed fluid path;

branching a container off [of] the closed fluid path and communicating the container fluidly with a circulator of the dialysate via one or more pumps {so as to be able] to increase a volume capacity of the fluid circuit [at a controlled flowrate] to compensate for an increase in fluid volume in the fluid circuit by moving fluid from the fluid circuit to the container and from the container to the fluid circuit at controlled flowrates with the one or more pumps;

removing an amount of solutes from the fluid as the fluid circulates along the closed fluid path; and

draining the fluid circuit of fluid after treatment. --

Claim 38 has been amended as follows: --

38. (Currently amended) A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a therapy fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a first source of a therapy fluid including a dialysate to the fluid circuit;

supplying a second source of the therapy fluid including an osmotic agent solution to the fluid circuit;

circulating the therapy fluid along the closed fluid path;

branching a container off [of] the closed fluid path and communicating the container fluidly with a circulator of the therapy fluid from the fluid circuit to the container and from the container to the fluid circuit at a controlled flowrate [so as to be able] to increase a volume capacity of the fluid circuit [at a controlled flowrate] to compensate for an increase in fluid volume due to the ultrafiltrate and the osmotic agent solution;

removing an amount of solutes including a therapeutically effective portion of urea from the therapy fluid as the therapy fluid circulates; and

draining the fluid circuit of fluid after treatment. --

Claim 45 has been amended as follows: --

45. (Currently amended) A method of providing peritoneal dialysis to a patient, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a therapy fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a first source of therapy fluid including a dialysate to the fluid circuit;

supplying a second source of the therapy fluid including an osmotic agent solution to the fluid circuit;

circulating the dialysate and the osmotic agent solution along the closed fluid path;

removing a therapeutically effective amount of solutes and ultrafiltrate from the therapy fluid including a therapeutically effective portion of urea; and

[draining] pumping fluid from the fluid circuit [of fluid] at a controlled and effective rate into a container via a pump and pumping the fluid from the container via the same pump or another pump into the fluid circuit to compensate for an increase in fluid volume due to the second supply of the therapy fluid and the ultrafiltrate. -- .

Claim 55 has been amended as follows: --

55. (Currently amended) A method of reducing an amount of dialysate used during dialysis therapy, the method comprising the steps of:

coupling a fluid circuit in fluid communication to a catheter in a peritoneal cavity of the patient thereby defining a closed fluid path along which a fluid is capable of being circulated to remove solutes and ultrafiltrate from the patient;

supplying a source of the fluid including a dialysate in an amount of about 6 liters or less to the fluid circuit;

circulating the dialysate along the closed fluid path;

branching a container off [[of]] the closed fluid path and communicating the container fluidly with a circulator of the dialysate at a controlled flowrate from the fluid path to the container and from the container to the fluid path [so as to be able] to increase a volume capacity of the fluid circuit to compensate for an increase in fluid volume in the fluid circuit [at a controlled flowrate] due to removal of the ultrafiltrate from the patient; and

removing an amount of solutes from the therapy fluid as the therapy fluid is continuously circulated. -- .

In the Specification; at page 12, in line 13 -- now Patent 6,976,973, -- has been inserted

after "2000," ; and on page 20, in line 20 -- 39 -- has been inserted after "number of pumps".

The following changes to the drawings have been approved by the examiner and agreed upon by applicant: Figure 3 must be amended to show a reference numeral for the feature identified as a circle denoting the claimed one or more pumps,. In order to avoid abandonment of the application, applicant must make this above agreed upon drawing change.

The following is an examiner's statement of reasons for allowance:

Independent claim 9 now distinguishes over the applied prior art of record in view of : "a reservoir coupled fluidly to the fluid circuit via the cycler and one or more pumps and branching off [[of]] the closed loop for moving fluid at a controlled flowrate from the fluid circuit to the reservoir and from the reservoir to the fluid circuit, and wherein the reservoir is adapted to provide a variable increase in volume capacity to the fluid circuit allowing the system to compensate for an increase in fluid volume in the fluid circuit during treatment ".

Independent claim 32 now distinguishes over the applied prior art of record in view of : "branching a container off the closed fluid path and communicating the container fluidly with a circulator of the dialysate via one or more pumps to increase a volume capacity of the fluid circuit to compensate for an increase in fluid volume in the fluid circuit by moving fluid from the fluid circuit to the container and from the container to the fluid circuit at controlled flowrates with the one or more pumps".

Independent claim 38 now distinguishes over the applied prior art of record in view of : "branching a container off the closed fluid path and communicating the container fluidly with a circulator of the therapy fluid from the fluid circuit to the container and from the container to the fluid circuit at a controlled flowrate to increase a volume capacity of the fluid circuit to compensate for an increase in fluid volume due to the ultrafiltrate and the osmotic agent solution".

Independent claim 45 now distinguishes over the applied prior art of record in view of : "pumping fluid from the fluid circuit at a controlled and effective rate into a container via a pump and pumping the fluid from the container via the same pump or another pump into the fluid circuit to compensate for an increase in fluid volume due to the second supply of the therapy fluid and the ultrafiltrate".

Independent claim 55 now distinguishes over the applied prior art of record in view of : " branching a container off the closed fluid path and communicating the container fluidly with a circulator of the dialysate at a controlled flowrate from the fluid path to the container and from the container to the fluid path to increase a volume capacity of the fluid circuit to compensate for an increase in fluid volume in the fluid circuit due to removal of the ultrafiltrate from the patient".

The changes made to each of the Independent claims 9,32,38 and 55 are supported by page 20, lines 4-11 and 18-21 of the Instant Specification.

Changes made to claim 45 are additionally supported by page 20, lines 11-13 and 16-18 of the Instant Specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve Griffin, can reached at 571-272-1189. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph Drodge
Primary Examiner

JWD

February 14, 2007